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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,879	08/12/2002	Pieter Cornelis Langeveld	246152016800	1306

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EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,879

Applicant(s)

LANGEVELD ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed on 3-23-2006 are acknowledged. Claims 1, 6 and 12 have been amended. Claims 1-6 and 12-13 are pending and currently under examination.

Claim Rejections Withdrawn

The new matter rejection of claim 12 under 35 U.S.C. 112, first paragraph, based on the limitation "natural compound inhibiting microbial growth" is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "test suitable for determining the presence or absence of an antimicrobial residue..." is withdrawn in light of the amendment thereto.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, for lacking an antecedent basis for the limitation "test" in line 1 is withdrawn in light of the amendment thereto.

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, for lacking an antecedent basis for the limitation "natural compound inhibiting microbial growth" in lines 1-2 is withdrawn in light of the amendment thereto.

The rejection of claims 1-6 and 12-13 under 35 U.S.C. 102(b) as being anticipated by Inglis et al. (Journal Assoc. Off. Anal. Chem. Vol. 61, No.5, 1978, pages 1098-1102 – IDS) is withdrawn in light of the amendment to claim 1. The newly amended claims now require that the mixture comprising the sample and the test composition be heated at the same time. This limitation is not present in the cited reference.

The rejection of claims 1-6 and 12-13 under 35 U.S.C. 102(b) as being anticipated by

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Katz et al. (Journal Assoc. Off. Anal. Chem. Vol. 61, No.5, 1978, pages 1103-1106 – IDS) is withdrawn in light of the amendment to claim 1. The newly amended claims now require that the mixture comprising the sample and the test composition be heated at the same time. This limitation is not present in the cited reference.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 2, 4, 6 and 12 under 35 U.S.C. 102(b) as being anticipated by Charm et al. (U.S. Patent 5,354,663) is maintained for reasons of record.

Applicant argues:

1. The facts of the present case are on point with *Perricone v. Medicis Pharm. Corp.*
2. The Federal Circuit determined that the District Court had improperly assumed what the prior art did not disclose or render inherent as issue was whether the prior art disclosed the application of its composition to skin sunburn not whether the prior art lotion, if applied to skin sunburn would inherently treat that damage.
3. The issue in the present case should not be whether prior art heating step, if applied to a sample would inherently inactivate compounds, but rather whether the cited references disclose inactivating compounds in a sample and test.

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4. The Examiner improperly assume what the prior art did not disclose or render inherent for if sunburn is not analogous to skin generally, then likewise inactivating any natural disturbing compounds present in the sample and test is not analogous to heating or incubating generally.
5. The Office has mischaracterized Charm as Charm does not disclose destroying “at least some of” the natural inhibitors in the sample.
6. Charm does not disclose the order of steps as claimed. Specifically, present claim 1 step ii) requires heating the contacted sample and test composition to inactivate any inhibiting compound. Hence step i) must occur before step ii). Charm dose not disclose such a step.
7. The Examiner appears to be mischaracterizing Charm’s spore-shocking step as a “second inactivating step”.

Applicant’s arguments have been fully considered and deemed unpersuasive.

With regard to Points 1-4, the fact pattern of *Perricone v. Medicis Pharm. Corp.* is not on point with the instant claims. *Perricone* dealt with whether a disclosure of administering a composition to skin generally, necessarily anticipates the application of said composition to sunburned skin. The question with regard to the instant claims is whether the same method steps anticipate non-disclosed effects. Moreover, with regard to *Perricone v. Medicis Pharm. Corp.*, the Federal Circuit stated if the art discloses the very same methods, then the particular benefits must naturally flow from these methods even if not recognized as benefits at the time (see page 6 of decision). As the method steps are deemed to be the same, the cited reference anticipates the rejected claims.

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With regard to Points 5-7, the instant claims require that the sample/test composition be heated at a temperature that would result in the inhibition of any compound naturally present that would inhibit growth of the test organism and subsequently incubating said sample/test composition.

As Charm et al. disclose a method for the determination of the presence of antimicrobial drugs in samples, the method comprising placing a sample into a container and heating the sample to a temperature of about 100 °C for one to five minutes, a temperature and time sufficient to destroy at least some of the natural inhibitors in the sample (see col. 3, lines 32-39). The method further comprises adding a test (test organism, i.e., a tablet of *Bacillus stearothermophilus*, the same organism as Appellants' test organism) to the sample, heating the mixture of the sample and the test to about 100 °C for 0.1 to two minutes (see column 3, lines 50-53), and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, lines 32-68), Charm et al. meets these limitations. Applicant is reminded that since open claim language is used, the initial heating step disclosed by Charm et al. does not preclude its use as an anticipatory reference. Moreover, since the disclosed temperature of the "rapid heating" step disclosed by Charm et al. falls within the range disclosed by the specification as being effective for the inhibition of any compound naturally present that would inhibit growth of the test organism, said step would necessarily inhibit said compounds.

The rejection of claims 1-6 and 12-13 under 35 U.S.C. 102(b) based upon a public use or sale of the invention is maintained for reasons of record.

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Applicant argues:

1. The Premi[®]Test egg protocol was disclosed after the filing date of the present application as exemplified by the attached leaflet.
2. The Geijp reference is drawn to the meat test as is apparent by the title.

Applicant's arguments have been fully considered and deemed non-persuasive.

The insert provided by Applicant is to a product named Premi[®]Test-egg which is a different product than that depicted in Exhibit B of Applicant's response filed on 10-7-2005. Said exhibit disclosed the use of the Premi[®]Test product with egg samples. The basis of the rejection is the date the Premi[®]Test was publicly disclosed and when the insert exemplified by Exhibit B was made publicly available. The Geijp reference was cited as evidence of the public availability of the Premi[®]Test. Exhibit B demonstrates that the Premi[®]Test constitutes the instant invention.

As outlined previously, the method that constitutes the instant invention is disclosed in the instruction sheet for the Premi[®]Test sample procedure for eggs (Exhibit B of Applicant's response filed on 10-7-2005). The procedure set forth in said instruction sheet anticipates all the limitations of the instant claims. Moreover, it is apparent the Premi[®]Test was publicly disclosed prior to the priority date of the instant application as evidenced by Geijp et al. (Abstract book "Third International Symposium of Hormone and Veterinary Drug Residue Analysis, Brugge", 1998).

An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b),

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additional information regarding this issue is required as follows: the date the Premi[®]Test became publicly available. The date the insert (exemplified by Exhibit B) was originally released.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. (U.S. Patent 5,354,663) for essentially the reasons set forth in the previous Office action in the rejection of claims 1-6 and 12-13.

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Applicant argues:

1. The Office has not demonstrated that the sample and the test organism are heated at a sufficiently high temperature to destroy the natural inhibitors in the sample and hence cannot be optimized.
2. Charm shows a heat-shocking step but said step is not a result effective variable that may be optimized.
3. The skilled artisan would not have applied Charm's method to an egg sample.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1 and 2, Charm discloses a test method for the determination of antimicrobial drugs in **food samples**, in which the test method includes placing a sample into a container and heating the sample to a temperature sufficiently high to destroy the natural inhibitors in the sample. The method further comprises adding a test microorganism to the sample, rapidly heat shocking said mixture; allowing said mixture to cool to (see example 1) to 80 °C to 85 °C and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, line 27, to column 4, line 10, in particular, column 3, lines 32-35). Charm et al. differs from the instant invention in that they do not explicitly disclose the temperature range and duration of heating with regard to samples comprising eggs. However, it is deemed, in absence of evidence to the contrary that the combination rapid heat shock/cooling period meets the time limitation set forth in claim 5.

With regard to Point 3, Applicant's argument appears to be off point, as the variable not explicitly disclosed in Charm was the time variable encompassed by claim 5. Applicant is

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reminded that Charm et al. disclose that their method can be used with a variety of foodstuffs and with no exclusionary statements being made with regard to egg products.

As, outlined previously, Charm et al. disclose a method for the determination of the presence of antimicrobial drugs in samples, the method comprising placing a sample into a container and heating the sample to a temperature of about 100 °C for one to five minutes, a temperature and time sufficient to destroy of the natural inhibitors in the sample (see col. 3, lines 32-39). The method further comprises adding a test (test organism, i.e., a tablet of *Bacillus stearothermophilus*, the same organism as Appellants' test organism) to the sample, heating the mixture of the sample and the test to about 100 °C for 0.1 to two minutes (see column 3, lines 50-53), allowing said mixture to cool to 80 °C to 85 °C, and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, lines 32-68). Moreover, Charm et al. disclose that the food or animal-derived sample may be heated with or without the test organism to inactivate any natural disturbing compound in the sample. During the second heating step, no interaction or reaction occurs between the test organism and the sample. It is plain that heating serves both to heat-shock the test organism (present as spores) and to inactivate any natural disturbing compound in the sample. Further, the open comprising language of the instant claims does not exclude additional steps, such as a second inactivating step. Whether the sample is heated once or twice before incubating it with the test organism, the result is the same. Applicant has not shown that the presence of a second inactivating step produces a different result. Both Charm et al. and Applicant perform the same steps in their methods and achieve the same result.

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-6 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The method steps set forth in the rejected claims seem to render said method inoperative. Applicant's argument that the claim amendment is sufficient to overcome the rejection is deemed non-persuasive. Step (ii) of claim 1 still requires that the test sample and the test composition to be heated until any compound that inhibits microbial growth in the sample is inactivated. This would encompass not only the antimicrobial substances that lead to false positives but also the antimicrobial residues that are to be detected. Consequently, one would not be able to get a positive result (i.e. detect an antimicrobial residue) utilizing the recited method steps.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 1 to recite, “any compound naturally present in the sample that is capable of inhibiting growth of the test microorganism leading to a false positive results absent said inactivating step...”. This phrase does not appear in the specification, or original claims as filed. The portion of the specification cited by Applicant for the basis for this limitation in the application does not support said limitation. Therefore this limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the phrase “compound naturally present in sample”. It is unclear what is meant by said term, as it is not explicitly defined in the specification. What constitutes being “unnaturally present”? As written, it is impossible to determine the metes and bounds of the claimed invention.

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Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ROBERT ZEMAN
PATENT EXAMINER

June 6, 2006